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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 683,548	01 16, 2002	John Austin Burns	38-21(51450)	7713

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MONSANTO COMPANY
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ST. LOUIS, MO 63167

EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,548

Applicant(s)

BURNS ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-23 are pending

Applicant's election with traverse of Group I, claims 1-20 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Applicants believe that it would not create an undue burden on Examiner to conduct a search encompassing all the claims. This is not found persuasive because while the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-23 are withdrawn from consideration because they are drawn to a non-elected invention.

2. Claims 1-20 are examined on their merits.

Specification

3. The specification is objected to for missing Table 1, page 21, paragraph 0093.

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons indicated on the enclosed form PTO-948. Correction is required. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 8, 9, 15, 16, 17, 19, and 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation "in a manner inducing" is not defined. Amending the claim to recite "to induce" will rectify the rejection. All subsequent recitations of "in a manner inducing" are also rejected.

Claim 8 contains the trademark/trade name Atrimmec. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe dikegulac and, accordingly, the identification/description is indefinite.

In claim 9, a space is needed in between "about" and "5000".

In claim 15, the phrase "explant portion" is unclear. Amending the claim to recite "explant" will rectify the rejection. All subsequent recitations of "explant portion" are also rejected.

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In claim 16, it is not clear if "an explant portion thereof" will include a meristem or primordium, as recited in claim 1.

In claim 17, it is not clear if "or portion thereof" will include a meristem or primordium, as recited in claim 1.

In claim 19, line 8, "explants" should be amended to "explant".

Claim 20 does not further limit claim 19. It is suggested that claim 20 be written as an independent claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the cotton plants claimed are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a cotton plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same cotton plants in each occurrence and it is not apparent if such cotton plants are readily available to the public. If the deposit of the cotton plants is made under

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the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the cotton plants will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

7. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims drawn to MS, MS/B5, GD1, Gamborg's, WPM, DKW culture medium to be used for tissue culture of embryo explants does not reasonably provide enablement for claims drawn to any modification of MS, MS/B5, GD1, Gamborg's, WPM, DKW LP, Nitsch

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and Nitsch, Shenk or Hildebrandt culture medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Applicants do not teach or disclose how the before mentioned media recipes are to be modified. Given the multitude of ingredients which comprise the different recipes, and the lack of guidance and examples that teach which ingredients can be added, deleted or substituted; given the plethora of chemicals that can be added to an existing recipe and the unpredictable results that are exhibited when extra ingredients are added to an existing culture medium, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 11-12, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bajaj et al (1986, Indian Journal of Experimental Biology 24:581-583, listed in IDS).

The claims are drawn to a method for regenerating a plant comprising culturing an explant comprising a shoot meristem or primordia on a medium comprising an apical dominance inhibitor and rooting the cultured explant to produce a plant. The claims are further limited to

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include an auxin wherein the auxin is IAA and the medium also includes a cytokinin wherein the cytokinin is BA or ZR and the plant is a cotton plant.

Bajaj et al teach a method of regenerating a cotton plant comprising culturing cotton shoot tips on MS medium comprising IAA and BA and producing multiple shoots from said explants which are subsequently grown into plants. In the present application, Applicants define "apical dominance inhibitor" to mean any non-cytokinin compound capable of promoting adventitious meristem production and lateral bud break (page 3, paragraph 0016). Promoting adventitious meristem production is interpreted by the Office to mean any compound that either negatively or positively is involved in adventitious meristem production. In Bajaj et al, the IAA and MS salts act to promote adventitious meristem production and as such, Bajaj et al anticipate the claimed invention.

9. Claims 1, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (November, 1992, U.S. Patent 5,164,310, listed in IDS).

The claims are drawn to a method for regenerating a transgenic plant comprising culturing an explant wherein the explant is a shoot meristem or primordia formed in vivo or in vitro, transforming an in vitro explant, culturing the transformed or non-transformed explant on media comprising an apical dominance inhibitor in a manner inducing bud or shoot formation from the transformed explant and rooting the transformed explant to produce a transgenic plant.

Smith et al teach culturing petunia seeds on sterile medium and excising shoot apices (column 3, last paragraph) which are transformed with *Agrobacterium* (column 4, 1st paragraph).

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Following inoculation and incubation, the shoot apices are cultured on medium (column 4, 4th paragraph). Smith et al disclose that the transformed tissue produced shoots which later formed roots (column 5, lines 1-6). The Applicants define "apical dominance inhibitor" as a non-cytokinin compound capable of promoting lateral bud break or adventitious meristem production. The Office interprets this definition to include the sucrose and MS salts of the method of Smith et al., as compounds that promote adventitious meristem production and as such, Smith et al anticipate the claimed invention.

10. Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Morre et al (1998, Plant Cell, Tissue and Organ Culture 54:131-136, listed in IDS).

The claims are drawn to a method for regenerating a plant comprising culturing an explant wherein the explant is the zygotic embryo or an explant portion thereof on a medium comprising an apical dominance inhibitor in a manner inducing bud or shoot formation from the explant and rooting the cultured explant to produce a plant.

Morre et al teach a method of regenerating a cotton plant comprising culturing cotton embryos on medium comprising MS macro- and micro-nutrients, B5 vitamins and glucose (page 132, "Plant regeneration" paragraph) and regenerating a plant from said explant (page 133, Figure 1C). The Applicants define "apical dominance inhibitor" as a non-cytokinin compound capable of promoting lateral bud break or adventitious meristem production (page 3, paragraph 0016). The Office interprets this definition to include the glucose, MS salts and B5 vitamins of the method of Morre et al., as compounds that promote adventitious meristem production and as such, Morre et al anticipate the claimed invention.

11. Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohamed-Yasseen et al (1990, PGRSA Quarterly 18(4):203-210).

The claims are drawn to a method for regenerating a plant comprising culturing an explant wherein the explant comprises a shoot meristem or primordial, culturing the explant on a medium comprising an apical dominance inhibitor in a manner inducing bud or shoot formation from the explant and rooting the cultured explant to produce a plant and wherein said plant is a soybean plant.

Mohamed-Yasseen et al teach a method of regenerating a soybean plant comprising culturing the embryo apex on medium comprising MS salts and N-phenyl-N-1,2,3-thiadiazol-5-yl-urea and indole-3-butyric acid (abstract). Whole plant were regenerated. The Applicants define "apical dominance inhibitor" as a non-cytokinin compound capable of promoting lateral bud break or adventitious meristem production (page 3, paragraph 0016). The Office interprets this definition to include N-phenyl-N-1,2,3-thiadiazol-5-yl-urea and indole-3-butyric acid of the method of Mohamed-Yasseen et al., as compounds that promote adventitious meristem production and as such, Mohamed-Yasseen et al anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-12, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bajaj et al (1986, Indian Journal of Experimental Biology 24:581-583, listed in IDS) taken with deSilva et al (1976, HortScience 11(6):569-570).

The claims are drawn to a method for regenerating a plant comprising culturing an explant comprising a shoot meristem or primordia on a medium comprising an apical dominance inhibitor wherein said apical dominance inhibitor is dikegulac and rooting the cultured explant to produce a plant. The claims are further limited to include an auxin wherein the auxin is IAA and the medium also includes a cytokinin wherein the cytokinin is BA or ZR and the plant is a cotton plant.

Bajaj et al teach a method of regenerating a cotton plant comprising culturing cotton shoot tips on MS medium comprising IAA and BA and producing multiple shoots from said explants which are subsequently grown into plants. In the present application, Applicants define "apical dominance inhibitor" to mean any non-cytokinin compound capable of promoting adventitious meristem production and lateral bud break (page 3, paragraph 0016). Promoting adventitious meristem production is interpreted by the Office to mean any compound that either negatively or positively is involved in adventitious meristem production. In Bajaj et al, the IAA and MS salts act to promote adventitious meristem.

Bajaj et al do not teach the apical dominance inhibitor dikegulac.

deSilva et al teaches the apical dominance inhibitor dikegulac.

Given the recognition of those of ordinary skill in the art of the value of regenerating a plant using a culture medium comprising an apical dominance inhibitor as taught by Bajaj et al, and given the definition of apical dominance inhibitor which is defined by Applicant as being

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any non-cytokinin compound that promotes adventitious meristem production, and given the teachings of deSilva et al who disclose the use of the apical dominance inhibitor dikegulac to promote axillary bud break in azaleas, and given the common practice of adding growth regulators to culture medium to promote growth and regeneration of plants in culture, it would have been obvious to include a compound into the culture medium to promote the production of many adventitious shoots off of an explant so that many plants can be regenerated from a single explant. In the instant application, it would have been obvious to include dikegulac in the culture medium to promote the production of many adventitious shoots from a single transformed or non-transformed explant.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

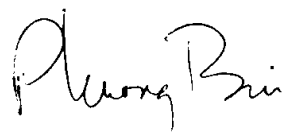
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-

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3014 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

Stuart Baum Ph.D.

November 26, 2002


PHUONG T. BUI
PRIMARY EXAMINER
11/26/02